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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,024	02/15/2002	G. Ganga Raju	IHEAL-01063US1	5778

23910 7590 03/03/2006

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EXAMINER

VANIK, DAVID L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,024

Applicant(s)

RAJU, G. GANGA

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/24/2005
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the Applicant's RCE and Amended Claims filed on 2/13/2006.

Claim Objections

Claims 26-27 are objected to because of the following informalities: Claims 26-27 are dependent on claim 1. Since claims 1-24 are cancelled, claims 26-27 are improperly dependent. The examiner assumes that Applicant meant to have the instant claims 26-27 depend from claim 25. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 recites the limitation "14-26% by weight of calcium; 24-40% by weight of potassium, and 14-24% by weight of sodium." Claims 26-27 appear to be dependent of claim 25, but have calcium, potassium, and sodium ranges outside of the instant claim 25. As such, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-30, 40-43, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 is drawn to a composition wherein said composition is "bound together to form a single molecule." There is nothing in the instant specification that describes a composition "bound together to form a single molecule."

Claim 29 is drawn to a composition comprising "less than approximately 4% by weight" of the lactone form of hydroxycitric acid. There is nothing in the instant specification that describes a composition comprising "less than approximately 4% by weight" of the lactone form of hydroxycitric acid. Rather, consistent with the instant specification, it is desirable that the lactone not exceed 2% of the composition (page 5, lines 1-3).

Claim 30 is drawn to a composition comprising "less than approximately 2% by weight" of sodium. There is nothing in the instant specification that describes a composition comprising "less than approximately 2% by weight" of the sodium. Rather, consistent with the instant specification, it is desirable that the composition have less than 1% by weight of sodium (page 4, lines 22-23).

Claim 40 is drawn to a composition comprising the constituents of claim 28 wherein said composition is administered in foods in beverages at a concentration of

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approximately 0.001 to 25% by weight of the total food or beverage. This claim is not supported by the instant specification. Rather, consistent with the instant specification, the hydroxycitric acid content can comprise approximately 0.001 to 25% by weight of the total weight of the food product (page 10, line 28 – page 11, lines 2).

Claim 41 is drawn to a composition comprising the constituents of claim 28 wherein said composition is administered in foods in beverages at a concentration of approximately 0.001 to 5% by weight of the total food or beverage. This claim is not supported by the instant specification. Rather, consistent with the instant specification, the hydroxycitric acid content can comprise approximately 0.001 to 5% by weight of the total weight of the food product (page 10, line 28 – page 11, lines 2).

Claims 26 and 42 are drawn to compositions comprising, in part, 5 to 12% by weight of sodium. These claims are not supported by the instant specification. Rather, consistent with the instant specification, the composition can comprise approximately 7 to 12% of sodium (page 4, line 30).

Claims 27 and 43 are drawn to compositions comprising, in part, 9 to 13% by weight of calcium. These claims are not supported by the instant specification. Rather, consistent with the instant specification, the composition can comprise approximately either 5 to 13% or 7 to 13% of calcium (page 4, line 19).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28, 31-38-39, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,612,039 in view of Clouatre et al ("The Diet and Health Benefits of HCA").

'039 teach a dietary supplementation composition comprising the calcium salt of Garcinia Cambogia-hydroxycitric acid extract (column 3, lines 5-14 and column 5, line 60 – column 6, line 29). According to '039, the Garcinia extract can be used to reduce appetite and assist in dietary control (column 3, lines 12-14 and column 5, lines 66-67). In terms of the dosage amount, about 750 mg may be administered to an individual prior to a meal (Claims 3-4). Since the compositions can be administered to an individual prior to breakfast, lunch, and dinner, it is the examiner's position that the

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compositions can be administered to an individual up to three times per day (Claims 3-5).

Although '039 teaches a hydroxycitric acid-based composition comprising calcium, it does not teach adding potassium to the weight loss composition.

Clouatre et al. ("The Diet and Health Benefits of HCA") suggest that potassium may augment the weight loss response of hydroxycitric acid (page 41). That is, it may be advantageous to combine potassium with hydroxycitric acid because such a combination could improve the weight loss capacity of hydroxycitric acid. Additionally, it is the examiner's position that the composition advanced by '039 has a negligible odor, is clear in solution, and has a minimal hygroscopicity. Because, according to Clouatre et al, the addition of potassium to a composition can augment the weight loss effects of hydroxycitric acid, one of ordinary skill in the art would have been motivated to add potassium to the hydroxycitric acid-based composition advanced by '039. Based on the teachings of '039 together with Clouatre et al., there is a reasonable expectation that a composition comprising potassium, calcium, and hydroxycitric acid would be an effective weight loss composition. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add potassium to the calcium/hydroxycitric acid-based composition advanced by '039 in view of the teachings of Clouatre et al.

Claims 25, 28-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,536,516 ('516) in view of in view of WO 98/28989 ('989).

'516 teach snack bars comprising hydroxycitric acid, nutrients, antioxidants, vitamins, or minerals (column 7, lines 1-10). According to '516, the concentration of hydroxycitric acid can be varied depending on the particular type of food product sought (column 7, lines 2-5). Based on this, it is the examiner's position that one of ordinary skill in the art at the time the invention was made would have the ability to alter the hydroxycitric acid percentage on the basis of the particular food product sought. Additionally, according to '516, other vitamins and minerals may be added to the snack bar compositions (column 7, lines 8-10). In terms of the physiochemical characteristics of the '516 composition, it is the examiner's position that the composition advanced by '516 has a negligible odor, is clear in solution, and has a minimal hygroscopicity.

'516 does not teach a composition comprising potassium, sodium, and hydroxycitric acid.

According to '989, the addition of between 0-30% calcium and 0-30 % potassium to a food product decreases obesity (page 2, lines 17-21). This is an unexpected result according to '989 (page 2, lines 21-22). Cookies or biscuits are food products suitable for use in the invention described by '929 (page 5, lines 16-17). It is the examiner's position that cookie or biscuit-like products are consistent with the snack bar products

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advanced by '516. Since, according to '989, the combination of calcium and potassium decreases obesity, one would be motivated to add it to the snack bar composition advanced by '516. Based on the teachings of '989 and '516, it is expected that a composition comprising hydroxycitric acid, calcium, and potassium would be an effective weight loss formulation. Accordingly, one of ordinary skill in the art at the time the invention was made would have been motivated to produce a snack bar comprising an effective amount of calcium, potassium, and hydroxycitric acid as suggested by the teachings of '989 and '516.

Response to Arguments

Applicant's arguments filed on 2/13/2006 have been fully considered but they are not persuasive. In response to the 10/25/2005 Final Rejection, Applicant asserts that one of ordinary skill in the art at the time the invention was made would not have sufficient motivation to combine the teachings of '516 with '989. The examiner respectfully disagrees with this assertion.

As set forth above, '516 teach a snack bar composition comprising hydroxycitric acid (claim 10). Along these lines, '929 teach that the addition of between 0-30% calcium and 0-30 % potassium to a food product, such as cookies or biscuit-like products, decreases obesity (page 2, lines 17-21). In response to Applicant's remarks, the fact that '989 does not specifically teach adding calcium and potassium to an anion is immaterial. It is the examiner's position that '989 still supplies motivation for adding calcium and potassium to snack bar-like compositions, such as biscuit-like products.

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Specifically, as set forth in '929, the addition of between 0-30% calcium and 0-30 % potassium to a food product, such as cookies or biscuit-like products, decreases obesity (page 2, lines 17-21).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 6,160,172 and US 6,395,296 are cited as patents of interest in their disclosures of soluble double metal salts of Group IA or IIA of hydroxycitric acid. However, because the instant application has a priority date of 7/14/1997, neither US Patent 6,160,172 nor US 6,395,296 is considered to be good prior art.

Correspondence


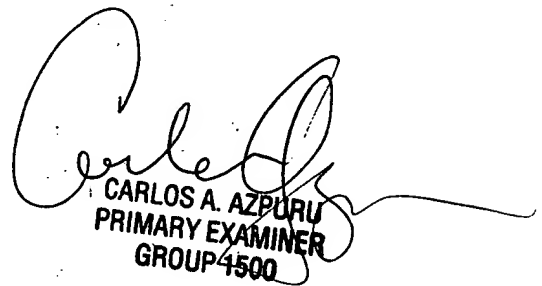
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
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2/28/06
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GROUP 4500